Supreme Court, U.S.
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No. _____

IN THE SUPREME COURT OF THE UNITED STATES

PETE SNYDER,
Petitioner,

v.

THE UPJOHN COMPANY,
Respondent,

On Petition for a Writ of Certiorari to the
United States Court of Appeals for the Ninth Circuit

PETITION FOR WRIT OF CERTIORARI

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QUESTIONS PRESENTED

Should evidence of a manufacturer's systematic suppression of scientific information about its product shift the burden under *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), from the consumer to the manufacturer?

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PETITION FOR WRIT OF CERTIORARI

Petitioner Pete Snyder respectfully prays that a writ of certiorari issue to review the decision of the Ninth Circuit Court of Appeals upholding the judgment against him herein.

ORDERS BELOW

The May 20, 1997, Memorandum and Order on Defendant's Summary Judgment Motion is attached hereto as Appendix A. The May 21, 1997 judgment is attached hereto as Appendix B. The February 12, 1999 Ninth Circuit Court of Appeals Memorandum is attached hereto as Appendix C. The June 10, 1999 order denying Petitioner's motions for rehearing and rehearing en banc is attached hereto as Appendix D.

JURISDICTION

This case was removed to the United States District Court for the Central District of California by Respondent on the basis of diversity under 28 U.S.C. sections 1332(a) (1) and 1441. On The May 21, 1997 judgment against Petitioner was entered in the United States District Court for the Central District of California. On February 12, 1999, the Ninth Circuit Court of Appeals affirmed. On June 10, 1999, the Ninth Circuit issued its order denying Petitioner's motions for rehearing and rehearing en banc. The jurisdiction of this Court is invoked under 28 U.S.C. § 1254(1).

CONSTITUTIONAL PROVISIONS AND STATUTES INVOLVED

Rules of Evidence for the United States Court and Magistrates, Rule 702.

If scientific, technical, or other specialized knowledge will assist the trier of fact to under the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill experience, training or education, may testify thereto in the form of an opinion or otherwise.

STATEMENT OF CASE

I would like to take the court through this as fast as possible. My misfortune happened on March 15, 1987. I had an accident with my wife on Sunday morning at about 8:30; I called 911, the police came, the fire engine came, the police took me away and the paramedics took my wife to the hospital. My wife died three days later on life support.

The sentencing was manslaughter; the judge gave me 11 years in state prison on August 11, 1987. During the time I was in state prison on August 21, 1989 we were locked down because of a stabbing in the yard as these people here in prison do that. As I was locked down in my cell, I had the Geraldo Rivera show on and they said "killer drug" so I watched it and then they mentioned Halcion. I looked up and said that was the sleeping pill that I took seven days before the accident with my wife. I jumped down and looked at my legal papers and there was the word Halcion in some pre-trial or final sentencing in my transcript.

From that moment on I was aware of what happened to me because my parents did not raise me to do something like this. I started to collect information on Halcion through the Freedom of Information Act. I saw articles in the paper, Time Magazine, 60 Minutes, CBS, the Phil Donahue show

and where I was first was aware, the Geraldo Rivera show. I obtained transcripts of all these shows.

I started to go to the law library and I found in Civil Procedures in California, I believe the cite is 340.2 of the California Civil Procedures. It stated therein that a prisoner incarcerated doing less than life term - that his statute of limitation on a civil matter was tolled. That I had one year after getting out of prison to file a civil complaint to Upjohn, the manufacturer of Halcion sleeping pills.

I was released from prison on January 29, 1993. I did 5-1/2 years on my sentence. I worked every day, I did not get any disciplinary actions and I did not lose any day because under California law we got day for day - if I worked one day I got a day off my sentence and I served exactly 5-1/2 years.

I filed the lawsuit on January 26, 1994, three days before the statute of limitations was up. I filed it in pro per and I am now back in pro per and I will tell you how this came about.

I filed the lawsuit in California Superior Court in Santa Monica, California. Upjohn put it in federal court on the basis of diversity. I learned now that if I filed my case and filed it against the doctor that prescribed Halcion sleeping pills to me it would have stayed in state court and I would not have gone through a Daubert hearing, which is why I am in front of the highest court in the land.

My case was in front of district Judge Wallace Tashima. For nine months I was without an attorney trying to answer their discovery, interlocutories, etc. I finally found an attorney that would take my case on a contingency and left it in his hands.

During that time, Judge Wallace Tashima was elevated to the Ninth Circuit and my new judge was District Court Judge King.

Between this time of 1994 to January 1996 there were discovery motions, depositions, etc. My expert witness was

Dr. Duke from Oslo, Norway. The lawyers for Upjohn were Shook, Hardy and Bacon. I have to say something here - Shook, Hardy and Bacon out of Kansas City, Missouri are the lawyers that have handled the tobacco industry for 40 years, a very large concern. During this time of discovery, my attorney went back to Kalamazoo, Michigan to look for documents in a warehouse of 20,000 square feet with documents in boxes piled high to the ceiling. I learned later that this was the big boo-boo. I learned that when I got back to pro per again and after the Daubert hearing, that Upjohn's attorneys have used work product-client privileges and withhold a crucial data base that they had. That is one thing that they did not disclose and it was unfair.

You can see on 95-U.S. Supreme Court, the case from Connecticut, where the court told Upjohn to give up the data base. This court confirmed what the Connecticut Supreme Court said. As you can see by the date of 95 (see Appendix I), my case was still in discovery and they played games and did not disclose to us on the data base so we did not have an even playing field.

Going back to the depositions and the cutoff date of discovery that I believe was November 29, 1995.

During deposition, or going over paperwork that was filed, my attorneys were working with one of their doctors and going through depos that were filed and paperwork that was filed, all of a sudden they came in with an affidavit, a statement that was done after the discovery cutoff date passed, they did this and sandbagged this information. I believe that in America I have the right to be fronted in person with my accuser, this is not England back in the old days. This statement was done after the discovery cutoff date of my wife's boss was over. It was derogatory, false and hurt me quite a lot. My attorneys wanted to be dismissed after this came in. They said it was financial disaster. I signed the

substitution of attorneys back to pro per because I didn't want attorneys that didn't want my case any more to stay on.

About February of 1996 I released my attorneys. At that time Upjohn gave me two more summary judgment motions. The two new ones that they gave me on summary judgments were causation and punitive damages. Both were answered around March of 1996. I am in pro per. I started immediately looking for another attorney. I had a very difficult time finding attorneys. I found out that Upjohn did the depositions, they paid for it, they asked the questions of my doctors and they got the information they wanted so they could use it in the summary judgments, etc.

So basically they were running the show, as I learned as I went through this case. This case is very interesting as to what happened to me and here I am fighting Shook, Hardy and Bacon out of Kansas City, the tobacco industry lawyers, with all these tobacco cases in the newspapers, etc.

I won the punitive damages summary judgment against them because the judge saw hanky-panky in the FDA investigation, the direction of all the lawsuits that were filed against them on Halcion in the last ten years and found prima facie that Respondent had engaged in systematic suppression of evidence (See Appendix E).

My case is probably one of the last Halcion cases, and I am having a hard time. When they settled their cases with other people they got a confidential agreement that no one says anything. That is why it was very hard for me to find that they had a data base. But it was probably too late.

And you can see on causation (See Appendix F) that the judge had said about a Daubert hearing and he told the plaintiffs and defendant that he wanted to have a master in reference to Daubert that he wanted to have someone keep the court informed on this and asked each of us to answer it and I answered it and said anything you want to do is okay with me, your honor. Shook, Hardy and Bacon answered it

by saying they are going to carry on in the courtroom if they go in that direction that the plaintiff will say he doesn't have any money and they will have to carry it.

Upjohn asked for reconsideration and the judge answered that order. The first civil minute order was April 23, 1996, and they then asked for a reconsideration, an interlocutory appeal and this was answered by the court on August 25, 1996 (See Appendices E and F).

From this point on, the judge was going to do the Daubert hearing himself. In between this time I was looking for an attorney. I found an attorney that would handle my case but he wanted to do a deposition on that affidavit that they sandbagged and knew that was after the cutoff date. So he told me to ask the judge for that.

I am in pro per and I asked to reopen discovery. There are things there that I did not know that I had to give a good reason or say it in that manner and I did mention it but they, Shook, Hardy and Bacon answered me saying that I should have asked for this ten months earlier when I first knew about it but I did not have an attorney so I did not know what to do. I answered their first summary judgment which was on causation and punitive damages. They pressed the court in their brief to deny me and to push for a Daubert date. And that's what happened. The judge made a date of January 14, 1997, I believe, for a Daubert hearing in his courtroom.

On the 14th of January, 1997 we had a Daubert hearing and there were three attorneys from Shook, Hardy and Bacon with a doctor named Rothschild. I was by myself, in pro per, without an attorney and I could not bring my doctor from Oslo, Norway because of finances and his business with the World Health Organization, with which he was working in Laos and Vietnam.

So I was by myself in the Daubert hearing. Judge King helped me in Daubert but he could not help me in all things.

He said, "Mr. Snyder, I am not saying that you lose but you hurt your case in not having the doctor here."

Shook, Hardy and Bacon explained what Daubert was and what the four factors of Daubert were, and they pounded about hearsay. I had a picture of Dr. Duke and, like the judge said, I kept giving them the same paperwork but I was in pro per and I didn't know what I was doing. He did not know the strength of the Halcion pill that I took: 0.5 mg - the FDA now uses only 0.25 or 0.125 strength (See Appendix G). He did not know what strength there was; that England bans Halcion, that France bans Halcion, Brazil, etc. In my cross-examination you could see that Judge King said "wait a minute - did I miss something?" And this was in reference to Dr. Rothschild's statement that he put an article in Britain's Lancet Journal after it was banned in England, quite a few years later. And, basically, Dr. Rothschild is a paid witness and that is what he does and, like they said, my Dr. Duke is only doing litigations and I do not understand all that (See Dr. Duke's Curriculum Vitae, Appendix H).

From that point on they started to give me documents that I didn't have from them before. Judge King said you will do closing arguments on paper, file a brief 20 page maximum, and exhibits. Upjohn's lawyers asked them "can we put in exhibits, there are records we want to enter in this case." The judge gave them permission.

We had a filing date about six weeks later and here comes Shook, Hardy and Bacon filing their brief and their exhibits, 54 of them, 2500 pages, against my little brief. They tried me in front of Judge King. I don't think I should have been tried before Judge King with everything they snuck in and they used that stated and pounded on it of my wife's boss that they took after discovery was over. So basically they did not play me fair. I did not have a level playing field and especially now that I found they had a data base that they did not give up.

With the judge's order in reference to the Daubert hearing, he used the four factors, he used things that they had in their 2500 pages. There is nothing in his opinion where it shows that he was flexible in using Daubert. I think the judge first of all should not have had a Daubert hearing and left the hearing of facts to a jury.

From that point on, I asked for reconsideration of the order of summary judgment on causation. I put in on my reconsideration facts from Dr. Duke stating he was in Laos, that the fax machines were not good to send it to me and his statement of what he thought of the Daubert hearing. I had a statement from him of what he thought of the Daubert hearing, which was notarized. His statement of affidavit.

Judge King entered summary judgment for Upjohn on May 21, 1997. I filed an appeal. I went and found an appellate attorney, a young man in Hemet. He had a shield that he was approved for the Ninth Circuit and I believe I was his first case in front of the Ninth Circuit Court of Appeal. We filed an appeal with the Ninth Circuit on time with judicial notice about the data base and everything. Looking at it now, I think he filed too much stuff. The clerks were looking at the case in the Ninth Circuit and I was ordered for oral argument of 20 minutes, not 10 minutes. I was excited, people tell me one out of 1,000 cases get oral arguments. There were a lot of things in my case but when the panel of the Circuit judges was picked one week before my date in front of the Ninth Circuit, they canceled oral arguments. I went to the court, I saw what happened. They submitted it on, I believe, the 3rd of February and in 10 days later or less I received my rejection from the Ninth Circuit - three pages - and it was all over with (See Appendix C). The one thing that the panel said was that Daubert is flexible, we know it is flexible and the judge knows its is flexible and we don't have to go into that argument.

I was confused. I filed a suggestion for rehearing en banc. Then on June 10, 1999 I received an order stating "rejected, no active judge has requested a vote." This must have gotten lost somehow because the suggestion is excellent.

REASONS FOR GRANTING THE WRIT

THIS COURT SHOULD GRANT REVIEW IN ORDER TO CONSIDER WHETHER THE MANUFACTURER'S SYSTEMATIC SUPPRESSION OF RELEVANT SCIENTIFIC INFORMATION SHIFTS THE BURDEN UNDER *DAUBERT V. MERRELL DOW PHARMACEUTICALS, INC.*, 509 U.S. 579 (1993) FROM THE CONSUMER TO THE MANUFACTURER

The District Court here found that Snyder made a prima facie case that Upjohn had systematically denied the scientific community access to unfavorable evidence about its product, Halcion. Yet, the District Court went on to use this Court's *Daubert* decision to deny Snyder the opportunity to present expert testimony as to the disastrous consequences of taking Halcion, because that testimony had insufficient support in the scientific community. In affirming, the Ninth Circuit explicitly held that there was "no need to relax the *Daubert* standard" despite the prima facie case that Upjohn's suppression of information contributed to that lack of scientific support

Snyder seeks review from this Court on the question of whether, as a matter of sound public policy, a pharmaceutical manufacturer shown to have systematically denied the scientific community access to negative information about one of its products should still be able to cast upon an injured consumer the *Daubert* burden of showing that the basis of the expert testimony he offers has the support of that scientific community..

Snyder's proof of Upjohn's misconduct was sufficient to overcome a motion for summary judgment on the issue of whether punitive damages would be available to Snyder under California law as a consequence of Upjohn's wrongdoing if its misconduct was proved at trial. The district court's memorandum decision failed to address this important aspect of the case, and in so doing, has turned *Daubert* on its head: The decision allows *Daubert's* gate-keeping mechanism to protect a defendant from potential liability even where the shortcomings in the plaintiff's expert-scientific-opinion evidence are presumptively shown to have been caused by the defendant's misconduct in suppressing unfavorable facts about its product bearing on the question under *Daubert* review, and which the plaintiff's expert and the scientific community at large have therefore been precluded from considering. If hiding unfavorable information can possibly enhance a pharmaceutical manufacturer's chances for insulation from liability by making plaintiffs' claims more vulnerable to summary dismissal because of *Daubert*, manufacturers will have little to lose and far too much to gain by methodically seeking to suppress all unfavorable information about the safety of their products.

The Ninth Circuit reasoned that the district court was aware of Snyder's charges of suppression and therefore presumably considered the argument among the factors it evaluated in making its *Daubert* determination. Snyder contends that prima facie evidence of evidence tampering and suppression must operate to shift the burden of proof on the issue of causation to the manufacturer under *Daubert*.

No case has considered the implications under *Daubert* of a defendant's misconduct in suppressing information relevant to a plaintiff's ability to produce scientific proof of its claim. This Court recently clarified its *Daubert* decision in *Kumho Tire Company, Ltd. v. Patrick Carmichael*, 119 S.Ct. 1167 (1999). Petitioner asks that this Court now

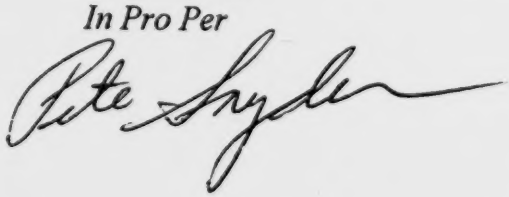
consider whether it should allow its *Daubert* decision to be used as an adjunct to the *suppression* of scientific information.

CONCLUSION

I suggest to this high court, to this lofty court, that you add on to the clarification you made of the Daubert gate-keeping function in *Kumho Tire Company, Ltd. v. Patrick Carmichael*,119 S.Ct.1167, *supra*, my suggestion that this Court not allow Daubert to be used to shield manufacturers who suppress the truth about their products. This case came out when my suggestion was in front of the Ninth Circuit en banc. I was shocked that they did not take this, I believe that my case in reference to obtaining punitive damages from Upjohn that I should not have had Daubert hearing at all, that I did not have a lawyer and my doctor was not there. My case should be sent back to the lower court for trial and this is what I am asking this court to do. I did not have a fair, level playing field with illegal, unethical practices by Shook, Hardy and Bacon. It just is not fair. I would please, please ask this court to please send this case back to the lower court for trial. I think that I don't have to meet the burden of Daubert in this action for reason of all that I have said here and the judge's reasoning of hanky-panky, the judge's ruling that he awarded me punitive of Upjohn. There is a lot of monkey business in cases that they have had with Halcion. I hope that this court gives me some love and grants this Petition.

Dated: August 30, 1999

Respectfully submitted,
Pete Snyder
In Pro Per



APPENDICES

APPENDIX A

UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

PETE SNYDER, Plaintiff, v. THE UPJOHN COMPANY, INC., Defendant.	)	No. CV-94-10826-GHK (AJWx) MEMORANDUM AND ORDER (Filed May 20, 1997)

DEFENDANT'S MOTION FOR SUMMARY JUDGMENT

I. Introduction

Plaintiff filed suit against defendant for product liability, alleging that ingestion of defendant's product, Halcion, caused plaintiff to strangle his wife. A plaintiff who brings a personal injury action must show a causal connection between the allegedly tortious behavior and the alleged injury. See Lust v. Merrell Dow Pharmaceutical, Inc., 89 F.3d 594, 595 (9th Cir. 1996). Defendant moves for summary judgment, asserting that plaintiff lacks admissible expert testimony going to the element of causation.

In a motion for summary judgment, a moving party who does not bear the burden of proof at trial need only point to an absence of evidence on an essential element in order to prevail. Here, Upjohn must show that plaintiff has not presented sufficient evidence to create a material dispute of fact as to causation.

II. Admissibility of Plaintiff's Evidence

The trial court determines preliminary questions of admissibility of evidence. Fed. R. Evid. 104(a). Because plaintiff's

proffered testimony regarding causation is in the nature of expert scientific testimony, the trial court's evaluation of its admissibility is guided by Federal Rules of Evidence 702, and the standards enunciated by the Supreme Court in Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 U.S. 579, 113 S.Ct. 2786 (1993) (Daubert I), and by the Ninth Circuit on remand, Daubert v. Merrell Dow Pharmaceuticals, 43 F.3d 1311, 1315 (9th Cir. 1995) (Daubert II).

A. The Daubert Standard

A district court's decision to admit evidence is based on two factors: (1) whether the testimony reflects "scientific knowledge," whether the findings are derived by the scientific method, and whether their work product amounts to good science; and (2) whether the proposed testimony is relevant in that it logically advances material aspects of the proposing party's case. Daubert I, 509 U.S. at 589-92, 113 S.Ct. at 2795-96. Four considerations may be appropriate in certain cases: (1) whether the theory or proposed scientific method can be and/or has been tested; (2) whether the theory or method has been subjected to peer review and publication; (3) is there a known or potential rate of error for a particular scientific method; (4) is the theory of method generally accepted in the scientific community. Id. at 593-94, 113 S.Ct. at 2796-97.

At bottom, the district court's duty is to determine whether the methodology, not the conclusions, satisfied Rule 702's requirement of reliability and relevance. "The inquiry envisioned by Rule 702, we emphasize, is a flexible one." Id. at 594, 113 S.Ct. at 2797. But no matter how flexible the gatekeeping role is, on occasion "authentic insights and innovations" may be kept from a jury, but this "is the balance struck by Rules of Evidence designed not for the exhaustive search for cosmic understanding but for the particularized resolution of legal disputes." Id. at 597, 113 S.Ct. at 2798-99.

1. Reliability

The Ninth Circuit agreed that the four factors suggested by the Supreme Court may not be applicable in all cases. Id. at 1316-

17. Rather than requiring strict adherence to this 4-part inquiry, the Ninth Circuit understood the Court to be "instructing us to determine whether the analysis undergirding the experts' testimony falls within the range of accepted standards governing how scientists conduct their research and reach their conclusions." Id. at 17. It identified the following factors.

a. Research Conducted Independent of Litigation

First, an expert opinion developed outside of the litigation context likely comports with the dictates of "good science," as bias is less likely to have influenced the particular conclusion and independent research usually must satisfy a variety of scientific standards to "attract funding and institutional support." Id.

A court may conclude that, despite plaintiff's representations to the contrary, his experts' opinions were in fact developed with an eye toward litigation. See Lust, 89 F.3d at 597 (though plaintiff's witness research was conducted before instant litigation, at the time of research the court found he was already a professional plaintiff's witness).

b. Objective Evidence of Scientific Validity

If the opinion was not based on independent research, the proponent of the testimony "must come forward with other objective, verifiable evidence that the testimony is based on 'scientifically valid principles.'" Daubert II, 43 F.3d at 1318. Typical "objective, verifiable evidence" might be evidence that the method has been subjected to scientific scrutiny through publication or peer review. Id. While publication would not guarantee correct conclusions, it indicates that "substantive flaws in methodology" would be detected.

c. Proffered Expert's Own Testimony as to Methodology's Scientific Validity

Finally, if plaintiff cannot present research done independent of litigation or an objective verifiable source that his method is sound, he may still be able to show valid scientific methodology

through the testimony of his own experts. This would require a precise explanation of how the expert conducted his study, how he reached his conclusions, as well as point to an objective source such as a treatise to show they have followed the scientific method as practiced by at least a minority of scientists in their field. Id. at 1319.

2. Relevance

To satisfy Rule 702's second element, the expert's testimony must have "valid scientific connection to the pertinent inquiry. . . ." Id. at 1320. In Daubert, as in the instant case, the pertinent inquiry was causation. Id. To determine whether the proffered testimony would assist the trier of fact, the Ninth Circuit looked to the governing California tort law on causation, which requires that plaintiffs show not just that a drug increased the likelihood of the injury, but that it more likely than not caused the injury. Id. (citing Jones v. Ortho Pharmaceutical Corp., 163 Cal. App. 3d 396, 403, 209 Cal. Rptr. 456 (1985)).

The Circuit recognized that application of this standard would, in some cases, prevent some plaintiffs whose injuries were attributable to the drug from recovering. However,

> [t]here is a converse unfairness under a regime that allows recovery to everyone that may have been affected by the drug. Under this regime, all potential plaintiffs are entitled to recover, even though most will not have suffered an injury that can be attributed to the drug. One can conclude from this that unfairness is inevitable when our tools for detecting causation are imperfect and we must rely on probabilities rather than more direct proof.

Id. at 1320, n. 13.

III. Applying Daubert

A. Reliability of the Experts' Proffered Testimony

Plaintiff submitted three proposed experts regarding general and specific causation of Halcion and homicidal behavior.

1. Dr. Maurice N.G. Dukes

Whether Dr. Dukes formed his opinion unrelated to this or other litigation involving Halcion is not entirely clear. While he has written on the subject of drug-induced injury prior to this litigation, one such publication, "the development of knowledge of adverse reactions to benzodiazepines," a 1991 report analyzing reviews by eleven experts, was compiled at the request of the U.K. Benzodiazepine Solicitor's Group. This suggests possible bias in that some research forming his opinion was conducted in relationship to or in anticipation of litigation.

Even if we were to accept that he developed his opinion unrelated to this or any other case involving Halcion, a benzodiazepine, we could not rest our inquiry there. Defendant is entitled to challenge the plaintiff's prima facie showing of admissibility. See Daubert II, 43 F.3d at 1318-19 n.10. As Dr. Dukes conducted no independent research on the effects of benzodiazepines, we cannot evaluate the reliability of his opinion by inquiring whether his "research method" was subject to publication or peer review. Id. at 1318. Rather, we must look to Dr. Dukes' own precise explanation of the scientific validity of his methodology. Id. at 1319. When we do, it becomes clear that Dr. Dukes' proffered testimony as to general and specific causation is inadmissible.

a. General Causation

Dr. Dukes relied on spontaneous report data and anecdotal cases reported in the pharmaceutical and medical literature to establish general causation. Dukes Depo., Ex. 53 at 201, 342, 346-47, 358. The facts in this case establish that spontaneous reports and anecdotal data cannot be used to come to general causation conclusions. Dr. Dukes himself testified that spontaneous reports in published literature cannot be used to determine cause and effect, or to quantify risk associated with a drug. Ex. 53 at 311-12, 342, 346-47. He agrees that spontaneous reporting data is used merely to

generate a hypothesis, and that the original data cannot be used to validate or confirm the hypothesis generated, but suggests that later data, "if it runs parallel to the earlier data," might be one way of validating or confirming the earlier data. Ex. 53 at 332-33. But Dr. Dukes also testified that he relied on spontaneous reports as "important evidence of causation," and that the only other material he relied on for general causation conclusions were individual "case reports," which are ultimately included by the FDA in their spontaneous reporting data. Ex. 53 at 347-48.

Defense expert Dr. Anthony Rothschild, whose testimony at the Daubert hearing we found credible, confirmed that reliance on anecdotal data "is not an acceptable method in the scientific community to prove causation." Transcript of Rothschild's testimony at Daubert hearing, Ex. 58 at 81; Rothschild Affidavits, Ex. 57 at paras. 2-11, 13-16.

b. Specific Causation

To reach his conclusion that Halcion caused plaintiff's injury in this particular instance, Dr. Dukes relied on "differential etiology" to rule out all other possible causes.

In conducting differential etiology, a physician first examines "all of the relevant data about the patient," including "the history of the current, present problem, past medical history, past psychiatric history, current medications that the person is on [and] past medication treatments," and "past history of violent behavior, whether the person had done anything like this before, substance abuse, alcohol abuse," to be followed by "an examination, physical examination and mental status examination" of the patient. Ex. 58, at 53-59. If a doctor misses or ignores significant relevant information about the patient, his conclusions would likely be wrong. Ex. 58 at 54.

Next, the physician lists all possible causes of the event. Ex. 58 at 54. The only possible causes which are eligible to appear on the list are those for which general causation has already been established. Ex. 58 at 55-56. Dr. Rothschild's testimony confirmed that conclusions regarding specific causation in a given patient are unreliable unless general causation is first established. Ex. 58 at 59.

Third, the physician examines the list of eligible possible causes and excludes them one by one, based on the data collected. Ex. 58 at 57; see, e.g., Claar v. Burlington Northern R. Co., 29 F.3d 499, 502 (9th Cir. 1994). If two or more possibilities remain on the list, a conclusion cannot be drawn. Ex. 58 at 58.

Dr. Dukes' use of differential etiology was flawed scientific methodology because, among other things, general causation had not been established to justify placing Halcion on the list of possible causes of plaintiff's injury.[1]

Thus, Dr. Dukes' testimony on both general and specific causation is inadmissible under Daubert because his conclusions were not reached by valid scientific methodology. Consequently, his opinions are unreliable and would not assist the trier-of-fact.

2. Dr. Spencer Eth

Like Dr. Dukes, Dr. Eth also relied on a review of spontaneous report data and anecdotal cases reported in medical literature to form a general causation opinion. Yet Dr. Eth conceded that it is not scientifically valid to draw causation conclusions from spontaneous reports of medical events, although they might provide "suggestive information." Ex. 54 at 164. As discussed in detail above, reliance on spontaneous reports and anecdotal data is flawed scientific methodology for forming general causation opinions.

Regarding his opinion on specific causation, Dr. Eth also used "differential etiology" to conclude that Halcion ingestion caused plaintiff's homicidal behavior. But as discussed above, only factors which have been shown to generally cause a reaction may legitimately be placed on a list of possible causes in any specific case. For this reason alone, Dr. Eth's testimony on specific causation would be inadmissible.[2]

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[1] Moreover, his performance of differential etiology may have also been flawed, in that he did not consider all relevant material in plaintiff's background.

[2] In addition, like Dr. Dukes, Dr. Eth may have conducted differential etiology improperly, failing to consider relevant background information.

3. Dr. Robert Julien

Defendant asserts that we must exclude Dr. Julien's testimony because plaintiff did not oppose defendant's motion regarding this expert, nor offer him as a witness at the Daubert hearing. Even if we reached the merits of Dr. Julien's proposed expert testimony, we would conclude that it too fails to meet Daubert's reliability and relevance tests. Dr. Julien also utilized differential etiology to reach his conclusion on specific causation, and based his opinion as to general causation on the opinions of Dr. Dukes.

Because plaintiff's proffered expert opinion testimony is inadmissible under Daubert, he submits no competent evidence to establish the element of causation. Therefore, defendant is entitled to judgment as a matter of law. Upjohn's motion for summary judgment is hereby GRANTED.

IT IS SO ORDERED.

Dated: This 20th day of May, 1997.

/s/ George S. King
GEORGE S. KING
UNITED STATES DISTRICT JUDGE

APPENDIX B

UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

PETE SNYDER,	)	No. CV-94-10826-GHK (AJWx)
Plaintiff,	)	
	)	JUDGMENT
v.	)	
	)	(Filed May 21, 1997)
THE UPJOHN COMPANY, INC.,	)	
Defendant.	)	

The Court having considered defendant's Motion for Summary Judgment, the opposition and reply briefs, the arguments of counsel and in accordance with the reasons stated in the court's memorandum and order;

IT IS HEREBY ORDERED that judgment is entered in favor of the defendant and against the plaintiff.

DATED: This 20th day of May, 1997.

/s/ George S. King
GEORGE S. KING
UNITED STATES DISTRICT JUDGE

APPENDIX C

NOT FOR PUBLICATION

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

PETE SNYDER, Plaintiff-Appellant, v. THE UPJOHN COMPANY, INC. Defendant-Appellee.	No. 97-55912 D.C. No. CV-94-01826-GHK MEMORANDUM[1] (Filed Feb. 12, 1999)

Appeal from the United States District Court
for the Central District of California
George H. King, District Judge, Presiding

Submitted February 3, 1999[2]
Pasadena, California

Before: PREGERSON, BEEZER, and HAWKINS,
Circuit Judges

Plaintiff alleges that his use of defendant's product, Halcion, caused him to strangle his wife in 1987. The district court

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[1] This deposition is not appropriate for publication and may not be cited to or by the courts of this circuit except as provided by Ninth Circuit Rule 36-3.

[2] The panel unanimously finds this case suitable for decision without oral argument. Fed.R.App.P.34(a)(2).

held a *Daubert* hearing on the admissibility of Snyder's proffered expert testimony and concluded that the evidence was unreliable and therefore inadmissible. The district court then granted summary judgment in favor of Upjohn. Snyder appeals.

Snyder argues that the district court erred by applying *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), to determine the admissibility of his experts' testimony. Whether *Daubert* applies is reviewed de novo. *See McKendall v. Crown Control Corp.*, 122 F.3d 803, 805 (9th Cir. 1997).

The district court properly subjected Snyder's proffered expert testimony to *Daubert* because the experts sought to give an opinion based on their scientific knowledge. *See id.* at 806. Plaintiff's argument that *Daubert* does not apply because his experts would testify based on their *specialized* - rather than *scientific* - knowledge is a misreading of *McKendall*. *See id.* at 807 ("specialized" knowledge is knowledge based on experience).

Having concluded that *Daubert* applies, we now turn to the issue whether the district court erred in applying *Daubert*. The district court found that the methodology used by Snyder's experts was unreliable and that their expert testimony was therefore inadmissible. Our review is for an abuse of discretion. *See Joiner v. General Elec. Co.*, 118 S.Ct. 512, 517 (1997).

Expert testimony should be admitted only if it is both reliable and relevant. *See Daubert*, 509 U.S. at 589. Snyder's proffered testimony is clearly relevant to whether Halcion caused Snyder to kill his wife. The issue, therefore, is whether the district court abused its discretion in finding the expert testimony unreliable and thus inadmissable under *Daubert*.

Snyder's experts used differential etiology to reach their conclusion that Snyder's use of Halcion caused him to kill his wife. The district court found their methodology flawed (1) because it limited Snyder's experts to only those causes for which general causation had been established in compiling their list of the possible causes of Snyder's behavior; and (2) because the spontaneous reports data Snyder's experts relied on to establish general causation cannot be used to establish cause and effect. As such, it is not clear whether Halcion should have even been on the list of possible

causes. The district court was therefore within its discretion in concluding that the evidence was unreliable.

Finally, Snyder argues that *Dabuert* should be applied less stringently in his case because he claims that Upjohns suppressed unfavorable information about Halcion and thus tainted any conclusions reach by the majority of the scientific community about the drug's effects. There is no need to relax the *Dabuert* standard. As this court has noted, the *Daubert* test is a flexible one. *See Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 43 F.3d 1311, 1317 (9th Cir. 1995) (the four "factors" enumerated by the Supreme Court are illustrative and not exhaustive); *see also Daubert*, 509 U.S. at 594 (indicating that the inquiry envisioned by the Federal Rules of Evidence is a flexible one). Furthermore, the district court was aware of the basis of Snyder's argument, and presumably considered it in ruling that the expert evidence he proffered was inadmissable. The district court deserves deference on this ruling. *See Joiner*, 118 S.Ct. at 517 (an overly stringent review of a district court ruling excluding testimony fails to give the trial court proper deference).

The district court properly subjected the proffered expert testimony to *Daubert*. The court was correct in excluding that testimony under *Dabuert*. Because Snyder presented no admissible evidence on the issue of causation, the district court's grant of summary judgment in favor of Upjohn is

AFFIRMED.

APPENDIX D

UNITED STATE COURT OF APPEALS
FOR THE NINTH CIRCUIT

PETE SNYDER,	)	No. 97-55912
	)	
Plaintiff-Appellant,	)	ORDER
	)	
v.	)	(Filed June 10, 1999)
	)	
THE UPJOHN COMPANY, INC.,	)	
	)	
	)	
Defendant-Appellee.	)	
	)	

Before: PREGERSON, BEEZER, and HAWKINS, Circuit Judges

The members of the panel that decided this case voted unanimously to deny the petition for rehearing. Judges Pregerson and Hawkins voted to reject the suggestion for rehearing en banc and Judge Beezer so recommends.

The full court has been advised of the suggestion for rehearing en banc and no active judge has requested a vote on whether to rehear the matter en banc. Fed.R.App.P.35.

The petition for rehearing is denied and the suggestion for rehearing en banc is rejected.

APPENDIX E

UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

CIVIL MINUTES–GENERAL

Case No. CV 94-1826-GHK (AJWx) Date: April 23, 1996

Title: PETE SNYDER v. THE UPJOHN COMPANY

PRESENT: Hon. George H. King, U.S. DISTRICT JUDGE

Shelley Keir	None
Deputy Clerk	Court Reporter

ATTORNEYS PRESENT FOR PLAINTIFF: None Present
ATTORNEYS PRESENT FOR DEFENDANTS: None Present

PROCEEDINGS: MINUTE ORDER (IN CHAMBERS)

This matter is before the court on defendant's six motions for summary judgment/adjudication on (1) the issue of proximate cause on plaintiff's failure to warn claim, (2) causation, (3) plaintiff's manufacturing defect claim, (4) statute of limitations, (5) collateral estoppel, and (6) punitive damages. See Fed. R. Div. P. 56. The court has considered the papers filed in support of, and in opposition to , defendant's motions and hereby orders the following:

1. *Intentionally omitted from appendix.*

2. Defendant's motion for summary judgment on the issue of causation is DENIED without prejudice at this time. The court views this issue as one involving the admissibility of plaintiff's experts' testimony. As such, and in light of the record, we conclude

that a Daubert hearing is required. The court will set the date for such hearing when appropriate. See infra.

The court is also contemplating the appointment of a court exert(s) to, among other things, advise the court during the course of the hearing. In addition, if the court concludes that plaintiff's evidence is sufficient to go to the jury, then the court-appointed expert(s) might also be asked to render an opinion on the issue of causation. The parties are hereby ordered to show cause in writing by May 7, 1996, why such expert(s) should not be appointed. See Fed. R. Evid. 706. After due consideration of the parties' positions, the court will issue such additional orders as are appropriate.

3. *Intentionally omitted from appendix.*

4. *Intentionally omitted from appendix.*

5. *Intentionally omitted from appendix.*

6. Finally, Upjohn moves for summary adjudication on the question of whether plaintiff has tendered admissible evidence in support of his claim for punitive damages pursuant to Cal. Div. Code § 3294(a). Defendant avers that Snyder's evidence cannot support a jury finding that Upjohn's conduct reveals "oppression, fraud, or malice. . . ." Oppression consists of "despicable conduct that subjects a person to cruel and unjust hardship in conscious disregard of that person's rights." Cal. Div. Code § 3294(c)(2). Plaintiff could recover exemplary damages for a "nondeliberate" personal injury by proving that Upjohn had acted with "conscious disregard of the safety of others." See G.D. Searle & Co. v. Superior Court, 49 Cal. App. 3d 22, 31-32, 122 Cal. Rptr. 218, 225 (1975). Behavior justifying the imposition of punitive damages under § 3294 could be proved either expressly "or by implication (by indirect evidence from which the jury may draw inferences)." Taylor v. Superior Court, 24 Cal. 3d 890, 894, 157 Cal. Rptr. 693 (1979) (quoting Bertero v. National Gen. Corp., 13 Cal. 3d 43, 66, 118 Cal. Rptr. 184, 201 (1974)).

To defeat this motion, plaintiff must tender admissible evidence enabling a reasonable jury to find, under a clear and convincing evidentiary standard, that Upjohn's actions met the statutory requirements. Plaintiff's evidence includes a copy of an FDA report co-authored by two of the agency's investigators, Michael Erspamer and Robert S.K. Young, M.D., describing an FDA investigation of Upjohn pertaining to Halcion. See Snyder Decl. Ex. 1. Six FDA investigators participated in this investigation, which was "intended to determine whether data originally submitted in support of the NDA for Halcion contained factually false information, or had damaging information withheld from the submission." Id.

Notwithstanding the fact that the FDA recalled the investigators before they had finished, this evidence supports an inference that Upjohn acted improperly vis a vis the FDA with regard to the approval and regulation of Halcion. For example, the report concludes that Upjohn sought "approval for long term use even though the evidence at hand suggested that use in excess of 14 days was potentially dangerous." Snyder Decl. Ex. 1 at 1. The report concludes that "data was misrepresented to the Agency in order to obtain approval for use longer than 14 days." Id. The report notes that Upjohn created a committee to defend negative publicity about Halcion and "suppress publication of unfavorable data and silence critics." Id. The sixty-five page report presents evidence that could be relied on by a finder of fact to conclude that Upjohn acted with "conscious disregard of the safety of others."

Upjohn maintains that the FDA report is inadmissible under the public records exception to the hearsay rule. See Fed. R. Evid. 803(8). We disagree, and find the report to be sufficiently trustworthy to merit admissibility under Rule 803(8). See Montiel v. City of Los Angeles, 2 F.3d 335, 341-42 (9th Cir. 1993) (public records and reports are presumed trustworthy, placing burden of establishing untrustworthiness on opponent of the evidence.

Subsection (c) of the Rule permits the admission of investigative reports containing conclusions and opinions if they were based on a factual investigation and satisfy the Rule's trustworthiness requirement. Beech Aircraft Corp. v. Rainey, 488

U.S. 153, 167-68, 109 S. Ct. 439 (1988). Whether an investigative report should be admitted under the 803(8)(C) exception is a matter within the "broad" discretion of the trial court. City of New York v. Pullman Inc., 662 F.2d 910, 914 (2d Cir. 1981), cert. denied 454 U.S. 1164 (1982); See also Smith v. Massachusetts Institute of Technology, 877 F.2d 1106, 1113 (1st Cir.), cert. denied 493 U.S. 965, 110 S. Ct. 406 (1989).

Upjohn's objections to the report fail to meet its burden of showing that the evidence is untrustworthy pursuant to Rule 803(8). See Montiel, supra, at 341. Defendant avers the report is untrustworthy because it is allegedly based on accounts and documents that were not created at or near the time of the acts or events described within them. The objection is not well taken in that neither Rule nor caselaw establishes a contemporaneity requirement. Defendant's unsupported characterization of the report as an interim or "draft" document is belied by the report itself. Moreover, the Rule, by its terms, admits "[r]ecords, reports, statements, or data compilations, in any form, of public offices or agencies. . . ." Fed. R. Evid. 803(8) (emphasis added). Although Upjohn correctly observes that the subject inspection was not completed, this fact fails to establish that the report is untrustworthy. Finally, defendant has provided no authority for the proposition that a government report is "untrustworthy" merely on the basis that it has not yet been formally adopted by an agency as its "official position." In sum, Upjohn's objections fail to establish the untrustworthy character of this report written by two FDA investigators after an official agency investigation by six FDA investigators.

In addition, Upjohn objects that the FDA report has not been authenticated. However, there is a reasonable basis for believing it can be properly authenticated. Given that plaintiff appears in pro per, it would be improper to deny him an opportunity to authenticate the report. Plaintiff is directed to refer to Rules 901 and 902 of the Federal Rules of Evidence pertaining to authentication. For the purposes of this motion, the evidence in Dr. Barry's deposition, see infra, suffices to support the punitive damages claim.

Plaintiff proffers the deposition testimony of Dr. William S. Barry, M.D., former Upjohn employee for thirteen years and former director of the Upjohn Drug Experience Unit. See Snyder Decl. Ex. 2. Considered in its entirety, the Barry deposition presents evidence that a reasonable finder of fact could rely on in finding Upjohn liable for punitive damages. The deposition indicates that Upjohn failed to include notice on the United States package insert for Halcion that the drug was associated with certain negative effects, long after the Drug Experience Unit advised Upjohn that this information about confusion, delusions, hallucinations, paranoia, aggression, and respiratory depression or arrest should have been included. Id. 47:7-49:25; 54:1-56:11. The deposition indicates that defendant established a"defense" committee to compensate for negative information about dangers of Halcion. Id., 59:23.

Dr. Barry also testifies that prior to a 1989 FDA Drug Advisory Committee meeting involving Upjohn-produced short half-life benzodiazepine drugs, including Halcion, Dr. Barry expressed concern that some false information was going to be presented to the FDA at the meeting. Id., 9:2-25. Barry attributed his subsequent removal from the directorship of the Upjohn Drug Experience Unit to a non-supervisory position to his expressed concerns regarding information to be provided to the FDA about the Upjohn drug Xanax. Id.

Moreover, the Barry deposition indicates that Dr. Barry and many other members of the Upjohn Drug Experience Unit believed that Halcion could be a contributing factor in creating a paranoid or delusional state. Id. at 136:15-22. Barry testified that he and the Unit felt that causality by Halcion between Halcion and hallucinations had been established by the end of 1983. Id., 56:1-13. Dr. Barry testifies that Halcion causality was also established for amnesia. Id.

Defendant contends the Barry deposition transcript is inadmissible because it is allegedly partial, unsigned, uncertified, and not authenticated. We find Upjohn's objections to be - at best - curious, in view of a November 20, 1995 correspondence from Upjohn counsel to plaintiff's former attorney stating:

> Pursuant to our conversation of Friday, November 17, in exchange for your agreement to forego a deposition of Dr. Barry in this case, we will provide the transcripts, videotapes and exhibits from the depositions of Dr. Barry in the Grundberg and Freeman cases to be used as if taken and noticed in this case.

See Statement of Genuine Issues in Support of Plaintiff's Opposition to the Upjohn Company's Motion for Summary Judgment on the Issue of Punitive Damages [Supplemental], Ex. 1. Accordingly, Upjohn has waived the above objections to the Barry deposition, which we find to be admissible evidence. Defendant's motion for summary adjudication on the punitive damages claim is DENIED.

IT IS SO ORDERED.

APPENDIX F

UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

CIVIL MINUTES–GENERAL

Case No. CV 94-1826-GHK (AJWx) Date: August 5, 1996

Title: PETE SNYDER v. THE UPJOHN COMPANY

PRESENT: Hon. George H. King, U.S. DISTRICT JUDGE

Shelley Keir	None
Deputy Clerk	Court Reporter

ATTORNEYS PRESENT FOR PLAINTIFF: None Present
ATTORNEYS PRESENT FOR DEFENDANTS: None Present

PROCEEDINGS: MINUTE ORDER (IN CHAMBERS)

This matter is before the court on defendant's motion for reconsideration, interlocutory appeal, and/or modification of this court's April 23, 1996 order on the issues of (1) proximate cause on plaintiff's failure to warn claim, (2) causation, (3) statute of limitations, (4) collateral estoppel, and (5) punitive damages. See Fed. R. Civ. P. 60(b); 28 U.S.C. § 1292(b). The court has considered the papers filed in support of, and in opposition to, defendant's motion and hereby orders the following:

1. *Intentionally omitted from appendix.*

2. Defendant's motion for reconsideration and/or for interlocutory appeal of the court's denial of its motion for summary judgment on the issue of causation is DENIED. In Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 U.S. 579, 113 S. Ct. 2786

(1993), the Supreme Court rejected the so-called Frye test in favor of a more flexible test devised under Fed. R. Evid. 702. The Court viewed the more flexible test as consistent with the "liberal thrust" of the Federal Rules of Evidence and the general approach of relaxing traditional barriers to "opinion" testimony. Id. at 2794. Essentially, the Court established a two-prong test. First, the evidence must reflect scientific knowledge, that is, the findings of the expert must be derived from valid scientific method, such that the work product amounts to good science. Id. at 2795, 2797. Second, the testimony must be relevant to the inquiry at hand, the so-called "fit" requirement. Id. at 2796.

The court set forth a list of four non-exclusive factors for courts to consider in weighing expert testimony under the first prong. It is clear, however, that these are not rigid factors that must be applied in every case. Indeed, there are instances where the nature of the proffered evidence is such that one or more of those factors may not be applicable. See Daubert v. Merrell Dow Pharmaceuticals, Inc., 43 F.3d 1311, 1316-17 & n. 4 (9th Cir.) (on remand), cert. denied, 116 S. Ct. 189 (1995). In fact, Daubert, on remand, teaches that even where the proffered evidence does not grow out of pre-litigation research, and the expert's research has not been subject to publication and peer review, expert testimony may be admissible if the experts "explain precisely how they went about reaching their conclusions and point to some objective source. . . to show that they have followed the scientific method, as it is practiced by (at least) a recognized minority of scientists in their field." Id. at 1318-19.

Nor is there any controlling authority suggesting that proof of causation necessarily requires epidemiological tests or studies. Defendant confuses the Ninth Circuit's discussion of the "fit" prong in its analysis in Daubert, which involved a reanalysis of epidemiological studies, with an alleged edict that only epidemiological studies are sufficient to meet the test of scientific admissibility under prong one for purposes of proving causation. See id. at 1320-21. Moreover, while defendant's expert may be of the opinion that only epidemiological studies provide valid scientific methodology, that is not dispositive of this issue.

For purposes of summary judgment, defendant must show that plaintiff's proffered expert testimony is inadmissible as a matter of law. Moreover, if defendant is of the view that no Daubert hearing is necessary, it must then show that plaintiff's expert testimony does not even rise to the level of a prima facie showing under the principles of Daubert. However, if plaintiff makes such a prima facie showing, and defendant contradicts plaintiff's expert's testimony, an evidentiary hearing is necessary for the court to determine as a matter of preliminary fact under Fed. R. Evid. 104(a) whether plaintiff's expert evidence may be presented to the trier of fact. Daubert, 43 F.3d at 1319 n. 10.

Given the foregoing, our task on this motion is to determine whether any of plaintiff's experts' testimony meets the prima facie test of admissibility under the Daubert principles. If so, then the motion for summary judgment must be denied, and a Daubert hearing must be held to determine whether such evidence may be presented to the jury. If so, then the matter must proceed to trial. If not, then summary judgment, or judgment as a matter of law, must be granted in defendant's favor.

First, we must view the expert testimony supporting plaintiff's causation theory in the context of the facts of this case. Unlike Daubert, where the issue was whether Bendectin caused certain physical deformations, the issue here is whether Halcion caused a certain psychiatric reaction in plaintiff which resulted in his killing his wife. We do not see the causation issue here as identical to that in Daubert and therefore do not slavishly adhere to the rigid factor by factor analysis suggested by defendant. In sum, we decline defendant's invitation to put the Halcion square peg into the Bendectin round hole.

In this case, plaintiff's experts do not rely on epidemiological studies. Instead, they appear to be of the view that there have not been any valid epidemiological studies, despite defendant's claim to the contrary. Because epidemiological studies are not part of the experts' methodology, Daubert's testability or error rate factors are not applicable in this context. Rather, given the context of the opinions proffered, the proper inquiry is whether the experts have precisely set forth the methodology used, and

whether such methodology is supported by some objective source. Id. at 1319.

Under this analysis, we find and conclude that at least with respect to Drs. Eth and Dukes, each has sufficiently met the foregoing prima facie requirements of admissibility. Dr. Eth's report sets forth his method of evaluating plaintiff in an accepted psychiatric protocol of psychological testing and clinical evaluation. Moreover, contrary to defendant's assertion, Dr. Eth's report shows that he has engaged in the methodology of differential etiology. Specifically, he set forth the potential causes of plaintiff's behavior and then discounted each potential cause except for plaintiff's ingestion of Halcion. As a board certified psychiatrist, Dr. Eth is qualified to engage in these accepted medical and psychiatric methods of diagnosis. See McCullock v. H.B. Fuller Co., 61 F.3d 1038, 1043 (2d Cir. 1995). Dr. Eths' report is therefore sufficient to state a prima facie case for admissibility pursuant to the Ninth Circuit's opinion in Daubert. See Daubert, 43 F.3d at 1319.

Similarly, Dr. Dukes' report sets forth his particular methodology, which also is in the nature of differential etiology. While defendant is correct to assert that Dr. Dukes is not qualified as a treating physician, this does not detract from his ability to incorporate a physician's report and opinion into his conclusions regarding a drug reaction, a subject on which he is an expert. Additionally, defendant's attack on Dr. Dukes' use of differential etiology is misplaced. Defendant's citation to parts of Dr. Dukes' deposition is, at best, taken out of context. Dr. Dukes did not testify that his opinion of causation was based on speculation, nor that his methodology is nothing more than speculation.

Defendant also argues that differential etiology methodology has not been recognized by the Ninth Circuit or the Supreme Court. However, this assertion is not dispositive of this issue. For our purposes, it is sufficient to note that neither the Ninth Circuit nor the Supreme Court has found differential etiology, especially as employed in medical diagnoses, insufficiently scientific. To the contrary, the Second Circuit has specifically rejected the argument that differential etiology does not qualify as scientific knowledge under Daubert. See McCullock, 61 F.3d at 1043.

We also reject defendant's argument that plaintiff's experts are not personally qualified to testify. Moreover, to the extent defendant challenges the second prong of the Daubert test, we reject such argument. Plaintiff's experts clearly testified that Halcion was the cause of plaintiff's behavior in killing his wife. This is more than adequate to defeat summary judgment considering that plaintiff need only prove causation by a preponderance of the evidence. Again, defendant is confused in uncritically relying on the discussion of "fit" in Daubert on remand. The "fit" analysis discussed in that case arose in relation to epidemiological studies, which lend themselves to that particular kind of statistical analysis. Because the methodology employed in this case is differential etiology, that statistical analysis is inapplicable to this case.

Based on the foregoing, summary judgment on the issue of causation is inappropriate. Moreover, because the Ninth Circuit test for admissibility of expert testimony is clearly set forth in the Ninth Circuit's opinion in Daubert, there is no "substantial ground for difference of opinion" justifying an interlocutory appeal on this issue. See 28 U.S.C. § 1292(b). The court reaffirms its view that a Daubert hearing is necessary to determine whether plaintiff's experts' testimony is admissible at trial. The court has also considered the parties' views on the court's order to show cause regarding the appointment of a court expert. We now reserve ruling on whether one or more court experts should be appointed to (1) assist the court in the Daubert hearing; and/or (2) testify at trial.

3. *Intentionally omitted from appendix.*

4. *Intentionally omitted from appendix.*

5. Finally, Upjohn moves for modification of the court's order to reflect that the FDA report tendered by plaintiff is inadmissible hearsay. Defendant maintains that the FDA report describing an FDA investigation of Upjohn pertaining to Halcion does not qualify under the public records exception to the hearsay rule. See Fed. R. Evid. 803(8). Defendant bases its entitlement to reconsideration on the court's purported failure to consider material

facts pertaining to Mr. Erspamer's deposition testimony. See Local Rule 7.16. However, the court did consider Erspamer's testimony, has re-considered it, and determines that the deposition testimony fails to meet Upjohn's burden of showing that the FDA report is untrustworthy pursuant to Rule 803(8). See Mot. Ex. G.

Defendant further argues that the report, summarizing an investigation by six FDA investigators and written by an FDA employee, is untrustworthy in that it purportedly is incomplete and reflects the "independent, personal views and conclusions of one FDA investigator." Mot. At 20. We disagree both with defendant's characterization of the report and understanding of the relevant caselaw. Subsection (C) of Fed. F. Evid. 803(8) permits the admission of investigative reports containing conclusions and opinions if they are based on a factual investigation and satisfy the Rule's trustworthiness requirement. See Beech Aircraft Corp. v. Rainey, 488 U.S. 153, 165-68, 109 S. Ct. 439 (1988). We find that the FDA report, based on a factual investigation, is sufficiently trustworthy to be admitted. See id. at 169. And of course it goes without saying that the admission of a report containing 'conclusions' is subject to the ultimate safeguard – the opponent's right to present evidence tending to contradict or diminish the weight of those conclusions." Id. at 168.

With respect to defendant's charge that the report is "interim" in character and therefore untrustworthy, we note that Rule 803(8) by its terms permits the admission of "[r]ecords, reports, statements, or data compilations, in any form, of public offices or agencies. . . ." See Fed. R. Evid. 803(8) (emphasis supplied). Moreover, defendant provides no authority for the proposition that a government report is untrustworthy solely because it has not been formally adopted by an agency as its "official position."[4] Finally, the alleged untimeliness of the writing of the

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[4] Compare City of New York v. Pullman, Inc., 662 F.2d 910, 914 (2d Cir. 1981), cert. denied, 454 U.S. 1164 (1982) (a report described by its own terms as "interim" and which failed to reach a conclusion on the relevant issue did not constitute findings of an agency as to that issue so as to qualify for Rule 803(8)(C) exception).

report does not dispose of the question of its trustworthiness, but rather comprises a single factor which we have considered but find insufficient to support defendant's position. See Beech Aircraft, 488 U.S. at 167 n. 11. Accordingly, defendant's motion for modification of our order as to admissibility of the FDA investigation report is DENIED.

IT IS SO ORDERED.

APPENDIX G

APPENDICES A AND B TO THE REPORT OF THE HALCION TASK FORCE U.S. FOOD AND DRUG ADMINISTRATION (May 29, 1996)

2. Group leader, HFD-120

The HFD-120 group leader provided the following history for Halcion: NDA 17-892 was filed in may 1976, reviewed and recommended for approval by an FDA advisory committee in 1977, but despite this recommendation, received a not approvable letter in 1977, citing insufficient preclinical data. The sponsor subsequently resolved this problem. During the 1977-1982 time frame, foreign experience was developed in the U.K., Canada, and the Netherlands. U.S. approval occurred in 1982 at a recommended dose of 0.25 - 0.5 mg in nongeriatric, nondebilitated adults. The FDA's approved labeling contained many of the adverse events that came to be associated with Halcion: amnesia, paradoxical reactions, confusion, memory impairment, agitation, and hallucinations.

Halcion entered the U.S. market in 1983. By 1987, excess adverse events reports for the drug product caused the FDA to modify the product labeling to lower the original starting dose from 0.25 - 0.5 mg to 0.25 mg. Upjohn also issued a *Dear Doctor* letter informing health professionals of this action. On approval, the PRECAUTIONS section of the Halcion labeling noted drowsiness, dizziness, and lightheadedness, with the possibility that these adverse events were dose related. This section of the label also was modified to emphasize that confusion, bizarre behavior, agitation, and hallucinations might occur following administration of Halcion, also with possibility of a dose relationship. In 1988, Upjohn discontinued the 0.5 mg strength.

Although spontaneous reports for the 1984-1987 time decreased, reports increased in the 1987-1988 time frame after the labeling was changed and the 0.5 m. dose was discontinued. Because this observation was in opposition to what might have been

expected, HFD-120 elected to discuss the matter before the Advisory Committee.

APPENDIX H

CURRICULUM VITAE: DR. M.N.G. DUKES

NAME: Dr. Maurice Nelson Graham Dukes

ADDRESS: Norway: Trosterudveien 19,
0386 OSLO
Tel. +47 22 49 40 58
Fax. +47 22 92 11 35

Denmark: Frödings Alle 10,
2860 SØBORG
Tel. +45 39 66 11 36
Fax +45 39 66 00 32

DATE OF BIRTH: November 2nd 1930

PLACE OF BIRTH: Barnsley, U.K.

NATIONALITY: British, Netherlands

MARITAL STATUS: Married

QUALIFICATIONS:

Medicine:

Physician (MRCS LRCP) 1956, MD 1963
St. John's College, Cambridge and
University College Hospital, London
University of Leiden (Netherlands)

Law:

Bachelor of Laws 1952
Master of Arts (Law) 1955
University of Cambridge

Master of Laws (Internat.Law) 1984
University of Cambridge 1984

SPECIALIZATION:

Adverse reaction monitoring
Medical risk management and assessment
Responsibility for drug-induced injury
Ethics of the pharmaceutical industry
Drug legislation and litigation
Pharmaceutical and health policies
Pharmaceutical economics

CURRENT POSITIONS:

A. Professor of Drug Policy Studies, University of Groningen, The Netherlands *(1985 to date)*
B. Senior Consultant on Drug Policies, The World Bank, Washington, D.C. *(1983, continuing)*
C. Editor in Chief, Meyler's Side Effects of Drugs *(1975 to date)*
D. Editor in Chief, Side Effects of Drugs Annuals *(1977 to date)*
E. Editor, The International Journal of Risk and Safety in Medicine *(1990 to date)*
F. Independent consultant on health policies, legislation, pharmaceutical systems and health litigation *(1991 to date)*
G. Managing Director, Euro Health Group *(appointment accepted temporarily: 1994/5)*

PREVIOUS WORK EXPERIENCE:

1982-1990: Head of the Pharmaceuticals Programme, World Health Organization, Europe
1972-1982: Medical Director, Netherlands National Drug Approval Agency
1957-1972: Research Manager, Organon International Pharmaceutical Industry
1955-1957: Medical Director, Richardson-Merrell Pharmaceuticals

PRINCIPAL BOOKS:

Meyler's Side Effects of Drugs (1975-1996)*
Side Effects of Drugs Annuals (1977-1994)*

These two books comprise the recognized international standard work on drug adverse reactions and are complemented by specialized volumes and a data base

Drug Utilization Studies (1993)*
Vitamins and Minerals: A Policy Outline (1992)*
Drugs and Money (6th Edition, 1991) Ø
Side Effects of Drugs Essays (1991)
Responsibility for Drug Induced Injury (1988) Ø
The Effects of Drug Regulation (1985)
De Toelating van Geneesmiddelen (1981)
Antidepressant Drugs (1966)*
Non-Steroidal Anti-Inflammatory Drugs (1964)*
Patent Medicines and Autotherapy (1963)

* = *Editor in chief*
Ø = *With Co-Author*

OTHER PUBLICATIONS:

253 scientific, technical and policy-orientated papers in the field of health policies, drug research and drug development, clinical pharmacology, clinical research, drug legislation, pharmaceutical policies and management.

DISTINCTIONS:

a. Chairman, Commission on "Gaps in Pharmaceutical Technology;" *Organization for European Co-Operation and Development*, Paris, 1967-1969
b. Chairman, Committee on Abuse of Medicaments; *Council of Europe*, Strasbourg, 1972-1974
c. Chairman, Committee on Clinical Standards; *Commission of the European Communities*, Brussels, 1978-1982

d. Chairman, Commission on Clinical Pharmacology, *Netherlands Health Council*, 1977-1982

e. Chairman, Commission on Future Scenarios for Drugs, *Netherlands Ministry of Health*, 1990-1994

APPENDIX I

No 95-1902

In The

Supreme Court of the United States

October Term, 1995

THE UPJOHN COMPANY,

Petitioner,

vs.

BEVERLY SCOVISH, Administratrix of the Estate of WALTER SCOVISH

Respondent.

On Petition for Writ of Certiorari to the Supreme Court of Connecticut

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RESPONDENT'S BRIEF IN OPPOSITION

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